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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,425	02/19/2002	Harold G. Brown	2059-0103P	1812

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EXAMINER	
UNDERDAHL, THANE E	
ART UNIT	PAPER NUMBER
1651	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	03/15/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 03/15/2007.

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mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	09/890,425	BROWN ET AL.	
	Examiner	Art Unit	
	Thane Underdahl	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *See Continuation Sheet* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 2,3,6-9,11-14,19,22,23,36,37,41,42,46-51,53,54,59,60,66,69,70,72-94,112-115 and 117-127.

Continuation of Disposition of Claims: Claims rejected are 2,3,6-9,11-14,19,22,23,36,37,41,42,46-51,53,54,59,60,66,69,70,72-94,112-115 and 117-127.

DETAILED ACTION

Claim Objections

Claim 117 is objected to as missing a space between the number "0.00005" and "mg" of the second to the last line of the claim. Also claim 66 is objected to as not being further limiting to its parent claim 41 or 42 since the Markush group of claim 66 is larger than the Markush group of either parent claim.

General Description of the Claims

Claims 2, 3, 6, 7, 8, 9, 11, 12, 13, 14, 19, 22, 23, 36, 37, 41, 42, 46-51, 53, 54, 59, 60, 66, 69, 70, 72-94, 112-115, 117-127 are directed to compositions comprising a complex carbohydrate from the group consisting of oligosaccharides, sialylated oligosaccharides, polysaccharides and glycosaminoglycan, which includes hyaluronic acid (also known as hyaluronan), in the absence of an essential oil. Also the complex carbohydrate contains up to 5% by weight of protein contaminants

The above claims will now be examined on the merits.

Claim Rejections - 35 USC § 112

Response to Applicants Remarks Filed on 5/10/06

The rejection of claim 93 under 35 U.S.C § 112 2nd paragraph is withdrawn in view of applicant's amendment.

Claims 122 and 123 remain rejected as being indefinite for containing new matter. Insertion of the limitation "carbohydrates are present in an amount of 0.0001 mg

to 100 mg" does not have support in the as-filed specification. The insertion of this limitation is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited genus which would show possession of the concept of the use of such a weight range in the compositions of claim 19 and claim 70. This is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Declarations and new references cannot demonstrate possession of a concept after the fact. Thus, the insertion of "carbohydrates are present in an amount of 0.0001 mg to 100 mg" is considered to be the insertion of new matter for the above reasons. While the applicant argues that "The Examiner's interpretation is in clear error as the specification does not limit the invention in the manner suggested" (Applicant's Response page 25, last two lines on the page) there is no evidence or specific argument provided that clearly establishes an error has occurred in the interpretation.

New Rejections Based on Amended Claims Filed on 5/10/06

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 49 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it

pertains, or with which it is most nearly connected, to make and/or use the invention. This claim is drawn to the prevention or treatment of a tumor.

While the state of the art is relatively high with regard to the treatment of specific cancer types, the state of the art with regard to treating cancer broadly is underdeveloped. In particular, there is no known anticancer agent that is effective against all cancer cell types.

The cancer treatment art involves a very high level of unpredictability. While the state of the art is relatively high with regard to the treatment of specific cancers with specific agents, it has long been underdeveloped with regard to the treatment of cancers broadly. The lack of significant guidance from the present specification or prior art with regard to the actual treatment of all cancer cells in a mammal, including a human subject, with the claimed active ingredient makes practicing the claimed invention unpredictable.

The claim is very broad and inclusive of cancer cells and tumors generally. The breadth of the claim exacerbates the complex nature of the subject matter to which the present claim is directed. The claim is extremely broad due to the vast number of possible cancer types represented by the term "tumors."

The specification does not enable any person skilled in the art to which it pertains (i.e. chemotherapy and treatment of cancer) to make or use the invention commensurate in scope with the claims. The lack of adequate guidance from the specification or prior art with regard to the actual treatment of all cancers with the complex carbohydrate composition fails to rebut the presumption of unpredictability

existent in this art. Applicants fail to provide the guidance and information required to ascertain which particular type of cancer the claimed anticancer agent will be effective against without resorting to undue experimentation. Applicant's limited disclosure is noted but is not sufficient to justify claiming all tumors broadly.

Absent a reasonable *a priori* expectation of success for using a specific chemotherapeutic agent/combination to treat any particular type of cancer, one skilled in the art would have to extensively test many various tumor types. Since each prospective embodiment, and indeed future embodiments as the art progresses, would have to be empirically tested, and those which initially failed tested further, an undue amount of experimentation would be required to practice the invention as its is claimed in its current scope, because the specification provides inadequate guidance to do otherwise.

Claim Rejections - 35 USC § 102

Response to Applicants Remarks Filed on 5/10/06

In response to applicant's amendment all 35 U.S.C § 102 and 103 rejections based on Balazs et al. (U.S. Patent # 4,303,676) are withdrawn.

Applicant also argues against the application of the Turley et al. reference (WO 97/25051, 1997) in the 35 U.S.C § 102(b) rejection. The applicant's argument is based on the misinterpretation of the molecular weight standards used to determine the molecular weight of carbohydrates in the compositions. The examiner acknowledges the receipt of the declaration under 37 CFR 1.132 which was considered but found not

persuasive. The arguments concerning the difference between the protein standard and dextran standard are not commensurate within the scope of the claims. The claims do not specifically mention how the molecular weight of the carbohydrates are determined but simply states "molecular weight ranges" and gives no indication on which method is used to obtain those ranges. Therefore the reference of Turley et al. still reads on the applicant's invention since the claims do no clearly state how the molecular weight of the carbohydrates are obtained.

New 35 U.S.C § 102 Rejections Based on Amended Claims Filed on 5/10/06

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2, 3, 6, 7, 19, 22, 23, 36, 37, 41, 42, 46-51, 53, 54, 59, 66, 69, 70, 72-76, 91-94, 112, 113, 115, and 117-127 are rejected under 35 U.S.C. 102(b) as being anticipated by Turley et al. (WO 97/25051, 1997)

Turley et al. discloses a product comprising a molecular weight hyaluronic acid fraction having a molecular weight in the range of about 30,000 to 2 million Daltons (page 5, lines 4-28) and specifically states 178,000 Daltons (page 7, line 16) in a pharmaceutical composition of a 1% by weight solution in sterile water that can be administered orally as a drink (page 5 lines 5-10). Turley et al. teach that the hyaluronic

acid used in their composition can use a pharmaceutical grade of hyaluronic acid that contains not more than (**NMT**) 0.10% by weight protein or a topical grade of hyaluronic acid that contains NMT 0.40% by weight protein (page 7 and 8, see Protein Content). Several claims recite the limitation that the complex carbohydrate "will cause an inflammatory response when injected into owl monkey eyes but will not cause an adverse reaction when applied to the skin of mammals or when delivered orally or mucosally to mammals" or the composition is "pharmacologically effective". These are functional limitations that define the composition by what it does rather than what it is (M.P.E.P. § 2173.05(g)) and as such since the composition meets the physical limitations of the composition it must therefore inherently meet the functional limitation.

Also claims 46-49 list several intended uses for the composition such as pain-relief and tumor prevention or treatment. Composition claims are evaluated based on their structural limitations. Intended uses such as those mentioned above do not provide any structural limitations to the composition and are therefore ignored (M.P.E.P. § 2111.02 II).

Therefore the reference anticipates claims 2, 3, 6, 7, 19, 22, 23, 36, 37, 41, 42, 46-51, 53, 54, 59, 66, 69, 70, 72-76, 91-94, 112, 113, 115, and 117-127.

Claim Rejections - 35 USC § 103

Response to Applicants Remarks Filed on 5/10/06

The 35 U.S.C § 103 (a) rejection over Turley et al. as applied above in view of Gallina (WO 92/22585, 1992) is withdrawn in view of applicants amendment.

New 35 U.S.C § 103 Rejections Based on Amended Claims Filed on 5/10/06

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2, 3, 6, 7, 11-14, 19, 22, 23, 36, 37, 41, 42, 46-51, 53, 54, 59, 66, 69, 70, 72-90, 91-94, 112, 113, 115, and 117-127 are rejected under 35 U.S.C. 103(a) as being unpatentable over Turley et al. (WO 97/25051, 1997) as applied to claims 2, 3, 6, 7, 19, 22, 23, 36, 37, 41, 42, 46-51, 53, 54, 59, 66, 69, 70, 72-76, 91-94, 112, 113, 115, and 117-127 with support from Sharma et al. (U.S. Patent # 4,933,183, 1990) and Weitzberg et al. (U.S. Patent # 5,079,260).

Claims 11-14 further limit the composition of claim 19 by requiring carbohydrates with a mixture molecular weight ranges. While this is not specifically taught by Turley et al. he does mention that their composition does contain dosage forms of hyaluraonan which the human body can easily use (page 5, lines 5-10). They define these two ranges of hyaluronan used by the body from 30,000 to greater than 2 million Daltons and the range 30,000 to greater than 70,000 daltons (page 4, lines 22-31). While Turley et al. teach using a composition with one molecular weight or the other it would be obvious for one of ordinary skill in the art to add both molecular weights (page 5, lines 4-30) according to M.P.E.P. § 2144.06 which states

> "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art."

Therefore it is *prima facie* obvious to one of ordinary skill in the art to add more sizes of hyaluronic acid to the composition of Turley et al. since he teach that both molecular weights can be used by the body to treat the same diseases such as heart attack and stroke.

Claim 13 limits the chemical composition of the complex carbohydrates as differing by molecular weight and chemical structure. However, these carbohydrates are polymers and their chemicals structure is dependant on molecular weight. Therefore since the molecular weights of Hyaluronic acid are different the chemical structure of the polymers must be different.

Claims 77-90 limit the final formulation of the composition. They limit the composition to a candy, mouthwash, tablet etc. While Turley et al. does teach an ingestible or topical composition they do not specifically teach these formulations. However it would be obvious to one of ordinary skill in the art to make ingestible formulations in these forms since these forms are obvious equivalents that are well known in the art (see M.P.E.P. § 2144.06) to make a medicament as supported by Sharma et al. (col 8, lines 31-50) and Weitzberg et al. (col 6, lines 18-30).

Therefore, the invention as a whole would have been prima facie obvious at the time of filing in view of the references listed above and as such claims 2, 3, 6, 7, 11-14, 19, 22, 23, 36, 37, 41, 42, 46-51, 53, 54, 59, 66, 69, 70, 72-90, 91-94, 112, 113, 115, and 117-127 are not allowable.

Claims 2, 3, 6-8 11-14, 19, 22, 23, 36, 37, 41, 42, 46-51, 53, 54, 59, 60, 66, 69, 70, 72-90, 91-94, 112, 113, 115, and 117-127 are rejected under 35 U.S.C. 103(a) as being unpatentable over Turley et al. as applied to claims 2, 3, 6, 7, 11-14, 19, 22, 23, 36, 37, 41, 42, 46-51, 53, 54, 59, 66, 69, 70, 72-90, 91-94, 112, 113, 115, and 117-127 above, and further in view of Taylor-McCord (U.S. Patent # 5,604,200, 1997).

The description of claims 2, 3, 6, 7, 11-14, 19, 22, 23, 36, 37, 41, 42, 46-51, 53, 54, 59, 66, 69, 70, 72-90, 91-94, 112, 113, 115, and 117-127 and how they are rendered obvious are detailed in the rejection by Turley et al. above.

Claims 8 and 60 limit their respective compositions by requiring the polysaccharide mannan. Turley et al. teach a topical composition that contains hyaluronic acid to be applied topically to the skin (page 14, lines 19-21) such as an wound site with scar tissue (page 14, lines 10-15). Taylor-McCord et al. teach a compositions for topical treatment of the skin that has been injured (col 8, lines 14-21) that also contains hyaluronic acid (col 11, Example II and col 12, Claim 1) that can have a concentration of hyaluronic acid of 0.05% to 2.00% by weight (col 12, claim 4) as well as Aloe Vera extract which one of ordinary skill in the art would recognize would contain mannas. It would have been obvious to someone skilled in the art to combine the

inventions of Turley et al. and Taylor-McCord since both teach a composition that contains hyaluronic acid for skin treatment and M.P.E.P. § 2144.06 states that,

> "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art."

Therefore it is *prima facie* obvious to one of ordinary skill in the art to add more Aloe Vera extract which comprises mannan to the a composition already comprising hyaluronic acid of Turley et al for topical treatment. Therefore the references listed above renders obvious claims 2, 3, 6-8 11-14, 19, 22, 23, 36, 37, 41, 42, 46-51, 53, 54, 59, 60, 66, 69, 70, 72-90, 91-94, 112, 113, 115, and 117-127.

Claims 2, 3, 6, 7, 9, 11-14, 19, 22, 23, 36, 37, 41, 42, 46-51, 53, 54, 59, 66, 69, 70, 72-90, 91-94, 112, 113, 115, and 117-127 are rejected under 35 U.S.C. 103(a) as being unpatentable over Turley et al. as applied to claims 2, 3, 6, 7, 11-14, 19, 22, 23, 36, 37, 41, 42, 46-51, 53, 54, 59, 66, 69, 70, 72-90, 91-94, 112, 113, 115, and 117-127 above, and further in view of Gaeta et al. (U.S. Patent # 5,559,103, 1996).

The description of claims 2, 3, 6, 7, 11-14, 19, 22, 23, 36, 37, 41, 42, 46-51, 53, 54, 59, 66, 69, 70, 72-90, 91-94, 112, 113, 115, and 117-127 and how they are rendered obvious are detailed in the rejection by Turley et al. above.

Claim 9 further limits the composition to comprise a sialylated sugar. While Turley et al. teach a composition comprising hyaluronic acid for the use of strokes or heart attack victims (see abstract). They do not teach the use of a sialylated sugar in their composition. This is taught by Gaeta et al. who teach a sialylated sugar for a pharmaceutical composition to treat patients of heart surgery (col 30 lines 59-62) and those who recently experienced a stroke or heart attack (col 31, lines 1-5). Since sialylated sugar compositions and hyaluronic acid compositions treat the same diseases it would have been obvious to someone skilled in the art to combine the compositions to treat heart and stroke victims. According to M.P.E.P. § 2144.06 which states

> "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art."

Therefore it is *prima facie* obvious to one of ordinary skill in the art to add sialylated sugars to the composition of Turley et al. Therefore the references listed above renders obvious claims 2, 3, 6, 7, 9, 11-14, 19, 22, 23, 36, 37, 41, 42, 46-51, 53, 54, 59, 66, 69, 70, 72-90, 91-94, 112, 113, 115, and 117-127.

In summary no claims, as written, are allowed for this application.

In response to this office action the applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for

interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

CONTACT INFORMATION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thane Underdahl whose telephone number is (571) 272-9042. The examiner can normally be reached during regular business hours, 8:00 to 17:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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